On September 23, 1939, the United States attorney for the District of Maine filed a libel against 39 packages of Hartshorn's Headache Powders at Portland, Maine, alleging that the article had been shipped in interstate commerce on or about July 22, 1939, by E. Hartshorn & Sons, Inc., from Northampton, Mass.; and charging that it was misbranded.

On October 9, 1939, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

80. Misbranding of Cephalgine Tablets. U. S. v. 30 Packages of Cephalgine Tablets. Default decree of condemnation and destruction. (F. D. C. No. 460. Sample No. 69431-D.)

This product consisted essentially of acetanilid, caffeine, and camphor. It would be dangerous to health when used as recommended, and its labeling failed to reveal the consequences which might result from its use. Its labeling was further objectionable because of false and misleading representations regarding its efficacy in the conditions indicated hereinafter.

On August 28, 1939, the United States attorney for the District of New Hampshire filed a libel against 30 packages of Cephalgine Tablets at Concord, N. H., alleging that the article had been shipped in interstate commerce on or about March 28 and April 20, 1939, by the Cephalgine Co. from Spencer, Mass.; and charging that it was misbranded.

It was alleged to be misbranded in that it was dangerous to health when used in the dosage or with the frequency prescribed, recommended, or suggested in the labeling, which recommended that a dose of one or two tablets be taken; that two more might be taken in 1 hour if needed or that two tablets might be taken every 3 or 4 hours and that, between the ages of 5 and 10, half the above dose should be administered; and because of failure of the labeling to bear warnings against use in those pathological conditions or by children where its use might be dangerous to health or against unsafe dosage or methods or duration of administration or application, in such manner and form as are necessary for the protection of users. It was alleged to be misbranded further in that statements in the labeling in which it was recommended as a relief of pain and discomfort due to simple headaches, neuralgia, and muscular aches and pains and in which it was represented that frequent use did not require an increase in the dose; that it contained no habit-forming drug or narcotic were false and misleading, since it was not a safe remedy for the conditions mentioned, and the said statements encouraged the user to take the preparation frequently and misled the user to believe that it might be taken with safety; whereas it contained a dangerous drug, acetanilid.

On October 18, 1939, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

81. Misbranding of Bromo-Seltzer. U. S. v. 168 Dozen Small Size, 102 Dozen Medium Size, 171 Dozen Large Size, 33 Dozen Extra Large Size, and 115 Dozen Dispensing Size of Emerson's Bromo Seltzer (and 7 other seizure actions instituted against Bromo Seltzer). Motion filed by claimant for consolidation and removal. Motion for consolidation granted. Motion for removal denied. Cases consolidated under one libel captioned U. S. v. 376 Dozen Small Size, et al. Emerson's Bromo-Seltzer. Consent decree of condemnation. Product ordered released under bond for salvaging the citric acid and the containers. (F. D. C. Nos. 184, 185, 186, 188, 189, 190, 191, 192, 195, 196. Sample Nos. 44847-D, 44848-D, 44861-D, 44862-D, 45051-D to 45057-D, incl., 45395-D to 45400-D, incl., 45501-D to 45514-D, incl., 59378-D, 59379-D, 59380-D, 59909-D to 59914-D, incl., 60061-D to 60071-D, incl., 60101-D, 60102-D.)

This product contained acetanilid, sodium bromide, and caffeine incorporated in an effervescing mixture. Seizure action was instituted on the charges that it was dangerous to health when used as directed in the labeling, and that its labeling failed to reveal facts material with respect to consequences which might result from its use.

On March 7, 8, and 10, 1939, the United States attorneys for the Southern District of New York, Northern District of Georgia, Eastern District of Tennessee, and the Middle District of North Carolina filed libels against a total of 1,116⅔ dozen small size, 798⅔ dozen medium size, 485¾ dozen large size, 101¾ dozen extra large size, 188¾ dozen dispensing size packages, and 20 cards, each bearing a number of individual dose tubes of Bromo Seltzer, in various lots at New York N. Y.; Atlanta, Ga.; Knoxville, Tenn.; and Greensboro, N. C., alleging that the article had been shipped in interstate commerce within the period from on or about October 31, 1938, to on or about March 8,

1939, by the Emerson Drug Co. from Baltimore, Md.; and charging that it was misbranded.

On April 25, 1939, the Emerson Drug Co., Baltimore, Md., filed in the Southern District of New York, a petition alleging that the 8 different libel proceedings involved identical issues, that it had acquired title to all the goods involved; that it had or would file a claim of interest in each proceeding and that it intended to defend and had answered or would file timely answers in each proceeding denying the material allegations of the libels. The intervenor petitioned that the proceedings be consolidated and removed to the United States District Court for the District of Maryland; and on April 26, 1939, an order to show cause why such consolidation and removal should not be ordered was served upon the Government. On May 9, 1939, the United States attorney having filed an affidavit in opposition to that portion of the relief prayed for which sought the removal of the consolidated proceedings to the District of Maryland, the motion for consolidation and removal was argued. Decision was reserved. On May 25 the court granted the motion for consolidation, but denied the motion for removal, handing down the following opinion:

JOHN W. CLANCY, *District Judge.* "This is a motion to consolidate eight libel proceedings into one and have it removed to the United States District Court for the District of Maryland, wherein the claimant, a Maryland corporation, has its principal place of business. The present proceedings are pending in the Southern District of New York, the Northern District of Georgia, the Eastern District of Tennessee, and the Middle District of North Carolina. The motion was brought under Sec. 304 (b) of the Federal Food, Drug, and Cosmetic Act, Title 21 U. S. C. A. 334, which provides in part: '* * * When libel for condemnation proceedings under this section, involving the same claimant and the same issues of adulteration or misbranding, are pending in two or more jurisdictions, such pending proceedings, upon application of the claimant seasonably made to the court of one such jurisdiction, shall be consolidated for trial by order of such court, and tried in (1) any district selected by the claimant where one of such proceedings is pending; or (2) a district agreed upon by stipulation between the parties. If no order for consolidation is so made within a reasonable time, the claimant may apply to the court of one such jurisdiction, and such court (after giving the United States attorney for such district reasonable notice and opportunity to be heard) shall by order, unless good cause to the contrary is shown, specify a district of reasonable proximity to the claimant's principal place of business, in which all such pending proceedings shall be consolidated for trial and tried. Such order of consolidation shall not apply so as to require the removal of any case the date for trial of which has been fixed. The court granting such order shall give prompt notification thereof to the other courts having jurisdiction of the cases covered thereby.' The Government has not objected to the consolidation but does object to the removal. The relevant portion of this section, in its original form in the Senate, provided: 'The United States District Court wherein the claimant's principal place of business is located, or such district court as the parties may agree upon, are hereby vested with jurisdiction to try such cases.' But the House changed it to read: '* * * (1) any district, selected by the claimant, where one of such proceedings is pending; or (2) a district in a State contiguous to the State of the claimant's principal place of business, such district to be agreed upon by stipulation between the parties, or, in case of failure to so stipulate within a reasonable time, to be designated by the court to which such application was made.' This change was not accepted by the Senate. The Bill was then sent to a Committee of Conference, whence it emerged in the form in which it was finally enacted. We think that the record of the Committee reports and debates in the Senate, preceding its enactment, and the Bill's language, disclose that it was the intention of the Congress that a claimant might not obtain a removal of the case for trial to the district of its principal place of business. The Act affords the claimant the right to obtain a trial in any other district of reasonable proximity to its principal place of business unless good cause to the contrary is shown. However, claimant here has not requested any district other than that of its principal place of business and, in the absence of such request, the Court, while granting the motion to consolidate, must deny the motion for removal, thereby effectuating a consolidation in this district which is reasonably proximate to claimant's principal place of business and wherein it saw fit to make this motion."

On May 31, an order was filed in accordance with the said opinion, and the Clerks of Court for the Eastern District of Tennessee, Northern District of

Georgia, and Middle District of North Carolina were ordered to transmit to the Southern District of New York all records in the proceedings in their respective jurisdictions. On July 21, 1939, after the cases were consolidated as ordered, an amended libel was filed in the Southern District of New York with respect to all the goods under seizure.

It was alleged in the said amended libel that the article was misbranded in that it was dangerous to health when used in the dosage or with the frequency prescribed, recommended, or suggested in the labeling. The dosage recommended on the cartons and bottle labels of the small, medium, and large sizes was a heaping teaspoonful in a half glass of water to be repeated in an hour if not relieved, or until 3 doses had been taken within 24 hours. The label of the extra large-size bottles and the dispensing size, the circulars enclosed in the cartons, and the single dose tube bore directions which were substantially the same, except that they recommended that the dose be repeated in a half hour if not relieved, or until three doses had been taken.

The article was alleged to be misbranded further in that the labeling was false and misleading because it failed to reveal facts material with respect to the consequences which might result from the use of the article under the conditions of use prescribed in the labeling.

The labeling which the libel alleged to be false and misleading consisted of the directions for dosage hereinbefore referred to and further statements appearing on the cartons enclosing all sizes but the single dose tubes, statements on the labels of the bottles enclosed in the said cartons, circulars accompanying the said bottles, the tubes containing the single dose size, and the cards to which the tubes were attached.

The said cartons bore representations that the article was a balanced compound of several medicinal ingredients for headache and neuralgia. The bottle labels bore the representation that the article was efficacious for the relief of headache and neuralgia. The single dose tubes and the cards bore representations that the article was efficacious for headache and neuralgia, that it was for use at home or while traveling and that it "Stops Headache Faster."

Circulars accompanying the small-, medium-, and large-sized bottles contained representations that millions had obtained "fast headache relief" with Bromo Seltzer; that it would relieve headache, settle the stomach, soothe the nerves, and "leave one keener the morning after"; that it would help the head and stomach when "too much to eat had caused a sick headache"; that it would be efficacious to "clear nervous headache" and leave one more efficient; that it would give rapid relief in fatigue headache; that doctors after testing a number of products which were popular for the symptoms of over-indulgence had found that Bromo-Seltzer relieved morning-after headaches faster than any other remedy they tested; that it would bring speedy relief to other types of headache; that it would relax nervous tension resulting from upset nervous system caused by headache, and would help place the nervous system in a more normal state; that it would help restore normal alkaline balance when accumulation of excess acid substances accompanied headache as on morning after; that a dose taken before going to bed, following over-indulgence or unusual strain or fatigue, would help prevent a headache next morning and that after waking another dose was added assurance against headache and hangover; and that its action, while prompt, was gentle and calming. A circular accompanying the extra large-sized packages contained representations that most people would rather have an occasional headache than observe the rigid rules necessary to avoid it; that certain pain-relieving drugs (like the one used in Bromo-Seltzer) had done more to give relief from headaches and ordinary discomforts and to make life more comfortable and agreeable than any other discovery of ancient or modern time; that it would save a holiday from being spoiled by headache which might follow strenuous exercise, muscle strain, exposure to the sun and wind; that it would end the pain of dull throbbing head resulting from exhaustion caused by overwork; that it should be taken at the first sign of a headache or before retiring at those times when one feels he may have a headache; that its granular effervescence made it the ideal form of headache remedy because besides stopping the pain in the head, the effervescence relieved gastric distress that so often accompanies, and even causes, headache; that for the most complete relief it should be taken in very cold water, a heaping teaspoonful to half a glass, stirred, and drunk at once since in that way it would be less bubbly and the greatest quantity of gas (CO_2) would remain dissolved in the water rendering its helpful action in the stomach more available; that its action while prompt was gentle and calming;

that one of two doses usually gave relief to periodic headaches of women; and that it does not upset the stomach.

On August 30, 1939, the claimant filed an amended answer, which denied the misbranding charges and challenged the constitutionality of the Federal Food, Drug, and Cosmetic Act on the grounds: first, that it provided for unlawful search and seizure; and second, that it was too general and uncertain in its provisions.

On January 2, 1940, the claimant having represented to the court that since the commencement of the several libel proceedings it had changed the formula of the product manufactured and sold by it, and the said claimant having consented to the entry of a decree, judgment of condemnation and forfeiture was entered. The decree contained the following provision: "*Ordered, Adjudged, and Decreed,* That this is a proceeding in rem and that this decree is to be without prejudice to the rights of the United States of America or of the said claimant. The Emerson Drug Company of Baltimore City, in any other litigation, and without prejudice to the right of the claimant to deny in any other or future litigation that the libeled product herein is misbranded or otherwise violates the provisions of the Federal Food, Drug and Cosmetic Act, the court having taken no proof in support of the allegations of the libel and answer."

On January 6, 1940, an order was entered by the court providing for release of the product under bond conditioned that the citric acid and the bottles be salvaged, and that the remaining ingredients of the product be destroyed.

DRUGS SEIZED BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS OR BECAUSE OF SUBSTITUTION[1]

VITAMIN PREPARATIONS

82. Adulteration and misbranding of cod liver oil. U. S. v. One 30-gallon Drum and Three 38-pound Drums of Cod Liver Oil. Default decree of condemnation and destruction. (F. D. C. Nos. 1082, 1083. Sample Nos. 55959–D, 55960–D.)

One lot of this product contained not more than 42.5 A. O. A. C. chick units of vitamin D per gram; whereas the United States Pharmacopoeia requires that cod liver oil shall contain not less than 85 U. S. P. units of vitamin D per gram (an A. O. A. C. chick unit of vitamin D is by definition the equivalent of a U. S. P. unit of vitamin D). The other lot was labeled as containing 400 U. S. P. vitamin D units per gram and 3,000 U. S. P. vitamin A units per gram, but contained not more than 50 A. O. A. C. chick units of vitamin D per gram and not more than 1,580 units of vitamin A per gram.

On November 28, 1939, the United States attorney for the Western District of Michigan filed a libel against one 30-gallon drum of cod liver oil and three 38-pound drums of cod liver oil at Petoskey, Mich., alleging that the article had been shipped in interstate commerce on or about September 15, 1939, by the Val-A Co. from Chicago, Ill.; and charging that it was adulterated and misbranded. It was labeled in part, "Val-A 'Cavalier'."

One lot of the article was alleged to be adulterated in that it was represented as a drug the name of which is recognized in an official compendium, and its strength differed from, and its quality and purity fell below, the standard set forth in such compendium. It was alleged to be misbranded in that the representation in the labeling that it contained 85 A. O. A. C. units of vitamin D was false and misleading.

The remaining lot was alleged to be adulterated in that its strength differed from, and its purity and quality fell below, that which it purported or was represented to possess. It was alleged to be misbranded in that the representations in the labeling that it contained 400 U. S. P. vitamin D units per gram and 3,000 U. S. P. vitamin A units per gram, were false and misleading.

On January 4, 1940, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

83. Adulteration and misbranding of cod liver oil. U. S. v. 4 Drums of Cod Liver Oil. Default decree of condemnation and destruction. (F. D. C. No. 700. Sample No. 48434–D.)

This product was labeled as containing 200 A. O. A. C. chick units of vitamin D per gram, whereas it contained not more than 135 such units of vitamin D per gram.

On October 9, 1939, the United States attorney for the District of Minnesota filed a libel against four 30-gallon drums of cod liver oil at Waseca, Minn.,

[1] See also N. J. Nos. 96 (Booth's Camphorated Oil and Carbolic Salve), 115, and 123.